

Application No.: 10/658,962
Attorney Docket No.: 49321-008US0
First Applicant's Name: Mendy S. Maccabee
Application Filing Date: September 8, 2003
Office Action Dated: December 29, 2009
Date of Response: June 29, 2010
Examiner: Jennifer M. Kim

REMARKS

Claims 1, 6-8, 21, and 24-28 are pending in this application. By virtue of this response, claims 1 and 6 have been amended. Support for these amendments may be found throughout the specification, such as, for example, paragraphs [0031] and [0046]. No claims have been cancelled or added. Accordingly, claims 1, 6-8, 21, and 24-28 remain under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Claim Rejections-35 USC §103(a)

Claims 1, 6-8, 21, and 24-28 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Vitamin A Metabolism In Nasal and Paranasal Diseases* by Masao Shigeyama ("Shigeyama") in view of U.S. Pat. No. 5,556,611 to Biesalski (U.S. "Biesalski"), U.S. Pat. No. 6,339,107 to Belloni ("Belloni"), and *Pretreatment of photoaged forearm skin with topical tretinoin accelerates healing of full-thickness wounds* to Popp et al. ("Popp"). The Examiner asserts that Shigeyama teaches that deficiencies in nutrients such as vitamins A and D are the cause of chronic paranasal sinusitis. Furthermore, although Shigeyama does not expressly teach topical delivery to the sinus cavity, the Office states that this would have been obvious to one of ordinary skill in the art in view of the teachings of Biesalski, Belloni, and Popp.

Applicants respectfully disagree with this rejection. Claim 1 has been amended to recite that the vitamin A composition is topically delivered to a sinus cavity from an implant placed in the sinus cavity. The cited references, alone or in combination, lack disclosure of these limitations. Indeed, none of the references teach or disclose topical administration of vitamin A to a sinus cavity, let alone vitamin A released from an implant placed in the sinus cavity. Shigeyama discusses only systemic administration of Vitamin A by intramuscular injection. *See, e.g.*, 58. Systemic administration of a substance is not equivalent or even analogous to topical

Application No.: 10/658,962

Attorney Docket No.: 49321-008US0

First Applicant's Name: Mendy S. Maccabee

Application Filing Date: September 8, 2003

Office Action Dated: December 29, 2009

Date of Response: June 29, 2010

Examiner: Jennifer M. Kim

administration, as each form of administration may have different dosage, absorption, distribution, and elimination profiles. Changing between systemic administration and topical administration is extremely unpredictable and Shigeyama provides no teaching that would support topical administration of vitamin A to the sinus cavity. Furthermore, as Shigeyama does not even discuss topical administration of vitamin A to the sinus cavity, it also does not teach or disclose administering vitamin A from an implant placed in the sinus cavity.

Additionally, Biesalski only discusses aerosol delivery of retinoic acid to the mucosa of the nose-throat cavity and preferably the “epithelia of the tracheal and deep bronchial tract,” and thus provides no teaching or suggestion of administration of vitamin A to the sinus cavity. *See, e.g.*, column 2, lines 15-20. Biesalski further fails to teach administration of vitamin A from an implant placed in the sinus cavity. Belloni and Popp also fail to cure these deficiencies. For at least these reasons, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Application No.: 10/658,962
Attorney Docket No.: 49321-008US0
First Applicant's Name: Mendy S. Maccabee
Application Filing Date: September 8, 2003
Office Action Dated: December 29, 2009
Date of Response: June 29, 2010
Examiner: Jennifer M. Kim

CONCLUSION

In view of the above, all pending claims in this application are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Application No.: 10/658,962
Attorney Docket No.: 49321-008US0
First Applicant's Name: Mendy S. Maccabee
Application Filing Date: September 8, 2003
Office Action Dated: December 29, 2009
Date of Response: June 29, 2010
Examiner: Jennifer M. Kim

Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7023

Respectfully submitted,
Mendy S. Maccabee et al.
Davis Wright Tremaine LLP

/Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Attorney for Applicant
Registration No. 47,309